Abstract

Substantially pure amorphous 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin A. In addition, this disclosure is directed to a process for the preparation thereof from crude 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin A via orthorhombic isostructural pseudopolymorphs of 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin A, of the general formula I

wherein S represents a water-miscible or water-immiscible organic solvent, characterized by the orthorhombic space group $P2_12_12_1$, with average unit cell parameters a=8.2 to 9.7 Å, b=11.5 to 13.5 Å, c=44.5 to 47.0 Å, $\alpha=\beta=\gamma=90^\circ$, wherein a, b and c represent the crystal axes lengths and α , β and γ represent the angles between the crystal axes.

In addition, pharmaceutical compositions containing the substantially pure amorphous 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin A are disclosed, as well as a method for the treatment of bacterial and protozoal infections, and inflammation related diseases in humans and animals by administration of a pharmaceutical composition containing same.